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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,679	12/05/2003	Jerry R. Colca	01012/1	9803

7590 06/28/2006

Pharmacia Corporation
Global Patent Department
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EXAMINER	
CHANDRA, GYAN	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/728,679	COLCA ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *8-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/12/05; 1/10/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-7, in the reply filed on 4/14/2006, is acknowledged.

Status of Application, Amendments, And/Or Claims

Claims 1-15 are pending.

Claims 8-15 are withdrawn from further consideration as being drawn to a nonelected Invention.

Claims 1-7 are under examination.

Information Disclosure Statement

The information disclosure statements (IDSs) filed on 5/12/2005 and 1/10/2006 have been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for screening compounds useful for treatment or diagnosis for type 2 diabetes, does not reasonably provide enablement for preventing

diabetes or for treating cancer, neurodegenerative disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to which the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986).

Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the

presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

The Nature of the Invention: The invention is drawn to identifying compounds useful for the treatment, prevention, or diagnosis of a mitoNEET associated metabolic dysfunctional diseases, cancer or neurodegenerative diseases including Parkinson's or Alzheimer's disease. The method comprises the step of determining whether said compound interacts directly with mitoNEET.

The state of the prior art and the predictability or lack thereof in the art:

Colca and Morton (IDS, New Antidiabetic Drugs, pages 255-261, 1990) teach that a number of thiozolidinedione compounds are known for reducing glucose level in mammals, therefore, the compounds are being used for the treatment of diabetes type II (conclusion, on page 259). However, the treatment of neurodegenerative disorders is far too complicated. The neurodegerative disorders include diseases such as Parkinson's disease, Alzheimer disease, Prion disease, Multiple Sclerosis (see, McGeer and McGeer, Brain Research Rev. 21: 195-218, 1995, for example). Each disorder is complex and could involve series of steps leading into these disorders. For example, McGeer and McGeer teach implications of inflammatory response in Alzheimer and other neurodegenerative diseases. James Vickers (page 487, first paragraph of Drugs Aging 19: 487-494, 2002) state that there are pharmaceutical interventions available that improve certain symptoms in a subset of affected individuals for a period of short time, but ultimately all cases follow the same progressive and degenerative path to

serve dementia. Vickers says that along with most brain diseases and conditions, there is no effective treatment currently available to reverse, slow down or prevent its course. Further, the phrase "prevention of a diseases", given its broadest reasonable interpretation with the specification, requires that absolutely no cell, nor tissue, would present any symptom of a disorder after treatment with the mitoNEET polypeptide. There is no evidence, either in the specification or in the prior art, that any method to date can accomplish this goal. The specification presents the results of binding of a specific protein with pioglitazone in a cross linking experiment, however there is no support for the prevention of any disorder, as is required by the claims, and neither can such support be obtained through reasonable extrapolation of the data.

The amount of direction or guidance present and the presence or absence of working examples: Given the teachings of unpredictability found in the art, detailed teachings are required to be present in the disclosure in order to enable the skilled artisan to practice the claimed invention. These teachings are absent. The specification also does not teach that the mitoNEET protein is involved in treating or preventing cancer or neurodegenerative disorders. The specification teaches that pioglitazone can be used to treat diabetes, and discloses on page 92, Example 4 that the polypeptide mitoNEET specifically binds with thiozolidinedione compound recited in claim 7 in a crosslinking experiment, and therefore the mitoNEET protein can be used to screen compounds that could be useful for treating diabetes. However, such compounds would not be useful for treating cancer or neurological disorder.

The breadth of the claims and the quantity of experimentation needed: Because the claims encompass a method of preventing diabetes or treating a cancer neurodegenerative disorder comprising administering the mitoNEET, in the light of the teachings of the unpredictability found in the art discussed and because of the supra lack of sufficient teachings in applicants disclosure to overcome those teachings, it would require undue experimentation by one of skill in the art to be able to practice the claimed invention in its full scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method of identifying compound that binds to mitoNEET. The phrase "mitoNEET" renders the claim indefinite because the specification discloses on page 1 as a family of proteins and as such the claims do not identify “mitoNEET” with any sequence identifier. Therefore, it is unclear whether “mitoNEET” is a polypeptide or a family of polypeptides.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1646
19 June 2006
Fax: 571-273-2922

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER